OCT 5 2010

Attachment B

510(k) Summary of Safety and Effectiveness
Prepared in accordance with 21 CFR Part 807.92(c).

K102256

GE Healthcare

GE Medical Systems (China) Co., Ltd
No. 19 Changjiang Road, National Hi-Tech Development Zone
Wuxi, Jiangsu Province, CHINA 214028

Section a):

1. Submitter: GE Medical Systems (China) Co., Ltd.
No. 19 Changjiang Road, National Hi-Tech Development Zone, Wuxi, Jiangsu Province, CHINA 214028

Contact Person: Yalan Wu,
Manager, Safety and Regulatory
Telephone: 86-510-85278652; Fax: 86-510-85227347

Date Prepared: June 20, 2010

2. Device Name: GE LOGIQ i/e, Vivid e Ultrasound
Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO
Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN
Diagnostic Ultrasonic Transducer, 21 CFR 892.1570, 90-ITX

3. Marketed Device: GE LOGIQ-i/e & Vivid-e Compact Ultrasound, 510(k) No: K091374 (90-IYO/IYN/ITX) A device currently in commercial distribution.

4. Device Description: The GE Compact Ultrasound is a very compact and portable diagnostic ultrasound system having three variations: LOGIQ i, LOGIQ e and Vivid e, each with options and features suited for its market niche. It has an integrated keyboard, LCD display and several interchangeable electronic-array transducers with an approximate size of 34 cm wide, 29 cm deep and 6 cm high in transport configuration and provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, an intuitive layout of specialized controls, color GUI display and Doppler audio.

5. Indications for Use: The subject modified device is a general purpose ultrasound system intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular; Intra-operative (abdominal, thoracic and PV), Musculo-skeletal Conventional & Superficial, Transesophageal, Transrectal and Transvaginal, and Thoracic/Pleural for motion/sliding and fluid detection.

6. Comparison with Predicate Device: The modified and unmodified Compact Ultrasound devices are virtually identical having the same design, construction, materials, brand names and intended uses. All technological characteristics and safety and effectiveness features are equivalent. The modified device has additional Transesophageal indication for use and Intima Media Thickness (IMT) measurement with Vascular.

Section b):

1. Non-clinical Tests: The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness, electromagnetic compatibility, as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards.

2. Clinical Tests: None required.

3. Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001:2000 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Healthcare that the GE LOGIQ i/e Vivid e Ultrasound imaging device is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

GE Medical Systems, Ultrasound and Primary Care Diagnostics, LLC
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

OCT 5 2010

Re: K102256
Trade/Device Name: GE LOGIQ i, LOGIQ e and Vivid e Diagnostic Ultrasound
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasound pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: September 27, 2010
Received: September 28, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the GE LOGIQ i, LOGIQ e and Vivid e Diagnostic Ultrasound, as described in your premarket notification:

Transducer Model Number

4C-RS	12L-RS	6S-RS
8C-S	16L-RS	P2D
E8C-RS	i12L-RS	6Tc-RS
8L-RS	i/t739-RS	
9L-RS	3S-RS	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use Form

510(k) Number (if known): _____

Device Name: GE LOGIQ i, LOGIQ e and Vivid e Diagnostic Ultrasound

Indications For Use:

The LOGIQ i/e & Vivid e is a general purpose ultrasound system intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular; Intra-operative (abdominal, thoracic and PV), Musculo-skeletal Conventional & Superficial, Transesophageal, Transrectal and Transvaginal, and Thoracic/Pleural for motion/sliding and fluid detection.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(Part 21 CFR 801 Subpart C)**

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Concurrence of CDRH, Office of In Vitro Diagnostics

for David G. Brown

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K102256

Diagnostic Ultrasound Indications for Use Form

GE Compact Ultrasound System

LOGIQ *i*, LOGIQ *e*, Vivid *e*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse†	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	P	
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ [2]	P	P	P		P		P	P	P	P	
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac[3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular	P	P	P	P	P		P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P	
Musculo-skeletal Superficial	P	P	P		P		P	P	P	P	
Thoracic/Pleural (specify)[4]	P	P	P	P	P	P	P	P	P	P	
Other[5]	P	P	P	P	P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal	N	N	N	N	N	N	N	N	N	N	
Transrectal	P	P	P		P		P	P	P		
Transvaginal	P	P	P		P		P	P	P		
Transuretheral											
Intraoperative	P	P	P		P		P	P	P	P	
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN and Urological

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] For detection of fluid and pleural motion/sliding;

[5] Other use includes Urology/Prostate

[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[†] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

Mark N. O'Kane for David G. Brown

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

Prescription Use (21 CFR 801 Subpart D)

510(k) K102256

Diagnostic Ultrasound Indications for Use Form

GE Compact Ultrasound with 4C-RS Transducer

LOGIQ *i*, LOGIQ *e*, Vivid *e*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse*	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P		P		P	P	P	P	
Abdominal[1]	P	P	P		P		P	P	P	P	
Pediatric	P	P	P		P		P	P	P	P	
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify)[4]	P	P	P		P		P	P	P	P	
Other[5]	P	P	P		P		P	P	P	P	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN and Urological

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] For detection of fluid and pleural motion/sliding;

[5] Other use includes Urology/Prostate

[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[*] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

for David G. Brown

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

Prescription Use (21 CFR 801 Subpart D)

510(k) K102250

Diagnostic Ultrasound Indications for Use Form

GE Compact Ultrasound with 8C-RS Transducer

LOGIQ *i*, LOGIQ *e*, Vivid *e*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]	P	P	P		P		P	P	P		
Pediatric	P	P	P		P		P	P	P		
Small Organ [2]	P	P	P		P		P	P	P		
Neonatal Cephalic	P	P	P		P		P	P	P		
Adult Cephalic											
Cardiac[3]	P	P	P		P		P	P	P		
Peripheral Vascular	P	P	P		P		P	P	P		
Musculo-skeletal Conventional	P	P	P		P		P	P	P		
Musculo-skeletal Superficial											
Thoracic/Pleural (specify)[4]	P	P	P		P		P	P	P		
Other[5]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN and Urological

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] For detection of fluid and pleural motion/sliding;

[5] Other use includes Urology/Prostate

[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[*] Coded Pulse is for digitally encoded harmonics .

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Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

Mark D Ökun for David G. Brown

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

Prescription Use (21 CFR 801 Subpart D)

510(k) K102256

Diagnostic Ultrasound Indications for Use Form

GE Compact Ultrasound with E8C-RS Transducer

LOGIQ *i*, LOGIQ *e*, Vivid *e*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/ Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	P	P	P		P		P	P	P		
Abdominal[1]	P	P	P		P		P	P	P		
Pediatric											
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify) [4]											
Other[5]	P	P	P		P		P	P	P		
Exam Type, Means of Access											
Transesophageal											
Transrectal	P	P	P		P		P	P	P		
Transvaginal	P	P	P		P		P	P	P		
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN and Urological

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] For detection of fluid and pleural motion/sliding;

[5] Other use includes Urology/Prostate

[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[*] Coded Pulse is for digitally encoded harmonics .

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Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

for David G. Brown

Prescription Use (21 CFR 801 Subpart D)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K102256

Diagnostic Ultrasound Indications for Use Form

GE Compact Ultrasound with 8L-RS Transducer

LOGIQ *i*, LOGIQ *e*, Vivid *e*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse†	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]	P	P	P		P		P	P	P	P	
Pediatric	P	P	P		P		P	P	P	P	
Small Organ [2]	P	P	P		P		P	P	P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	P	P	P		P		P	P	P		
Peripheral Vascular	P	P	P		P		P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P		P	P	P		
Musculo-skeletal Superficial											
Thoracic/Pleural (specify) [4]											
Other[5]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]	P	P	P		P		P	P	P		
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN and Urological

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] For detection of fluid and pleural motion/sliding;

[5] Other use includes Urology/Prostate

[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[†] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

Robert P. Phillips for David G. Brown

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

Prescription Use (21 CFR 801 Subpart D)

510(k) K102256

Diagnostic Ultrasound Indications for Use Form

GE Compact Ultrasound with 9L-RS Transducer

LOGIQ *i*, LOGIQ *e*, Vivid *e*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse*	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal [1]	P	P	P		P		P	P	P	P	
Pediatric	P	P	P		P		P	P	P	P	
Small Organ [2]	P	P	P		P		P	P	P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	P	P	P		P		P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P	
Musculo-skeletal Superficial											
Thoracic/Pleural (specify) [4]											
Other[5]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]	P	P	P		P		P	P	P	P	
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN and Urological

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] For detection of fluid and pleural motion/sliding;

[5] Other use includes Urology/Prostate

[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[*] Coded Pulse is for digitally encoded harmonics .

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Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

David G. Brown

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

Prescription Use (21 CFR 801 Subpart D)

510(k) K102256

Diagnostic Ultrasound Indications for Use Form

GE Compact Ultrasound with 12L-RS Transducer

LOGIQ *i*, LOGIQ *e*, Vivid *e*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse*	
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric	P	P	P		P		P	P	P	P	
Small Organ [2]	P	P	P		P		P	P	P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P		P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P	
Musculo-skeletal Superficial	P	P	P		P		P	P	P	P	
Thoracic/Pleural (specify) [4]	P	P	P		P		P	P	P	P	
Other (specify) [5]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative [5] (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN and Urological

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] For detection of fluid and pleural motion/sliding;

[5] Other use includes Urology/Prostate

[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[*] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

for David G Brown

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

Prescription Use (21 CFR 801 Subpart D)

510(k) K102250

Diagnostic Ultrasound Indications for Use Form

GE Compact Ultrasound with 16L-RS Transducer

LOGIQ *i*, LOGIQ *e*, Vivid *e*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse[*]	
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric	P	P	P		P		P	P	P	P	
Small Organ [2]	P	P	P		P		P	P	P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P		P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P	
Musculo-skeletal Superficial	P	P	P		P		P	P	P	P	
Thoracic/Pleural (specify) [4]											
Other (specify) [5]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative [5] (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN and Urological

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] For detection of fluid and pleural motion/sliding;

[5] Other use includes Urology/Prostate

[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[*] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

for David G. Brown

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

Prescription Use (21 CFR 801 Subpart D)

510(k) K102256

Diagnostic Ultrasound Indications for Use Form

GE Compact Ultrasound with i12L-RS Transducer

LOGIQ *i*, LOGIQ *e*, Vivid *e*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse*	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]	P	P	P		P		P	P	P	P	
Pediatric	P	P	P		P		P	P	P	P	
Small Organ [2]	P	P	P		P		P	P	P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	P	P	P		P		P	P	P		
Peripheral Vascular	P	P	P		P		P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P		P	P	P		
Musculo-skeletal Superficial	P	P	P		P		P	P	P		
Thoracic/Pleural (specify)[4]											
Other[5]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]	P	P	P		P		P	P	P		
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN and Urological

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] For detection of fluid and pleural motion/sliding;

[5] Other use includes Urology/Prostate

[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[*] Coded Pulse is for digitally encoded harmonics .

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Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

for David G Brown

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

Prescription Use (21 CFR 801 Subpart D)

510(k) K102256

Diagnostic Ultrasound Indications for Use Form

GE Compact Ultrasound with i/t739-RS Transducers

LOGIQ *i*, LOGIQ *e*, Vivid *e*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]	P	P	P		P		P	P	P		
Pediatric	P	P	P		P		P	P	P		
Small Organ [2]	P	P	P		P		P	P	P		
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	P	P	P		P		P	P	P		
Peripheral Vascular	P	P	P		P		P	P	P		
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify) [4]											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]	P	P	P		P		P	P	P		
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN and Urological

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] For detection of fluid and pleural motion/sliding;

[5] Other use includes Urology/Prostate

[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[*] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

for David 6. Brown

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

Prescription Use (21 CFR 801 Subpart D)

510(k) K102256

Diagnostic Ultrasound Indications for Use Form

GE Compact Ultrasound with 3S-RS Transducer

LOGIQ *i*, LOGIQ *e*, Vivid *e*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse†	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	P	
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac[3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify)[4]	P	P	P	P	P	P	P	P	P	P	
Other[5]	P	P	P	P	P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN and Urological

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] For detection of fluid and pleural motion/sliding;

[5] Other use includes Urology/Prostate

[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[†] Coded Pulse is for digitally encoded harmonics .

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Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

for David G. Brown

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

Prescription Use (21 CFR 801 Subpart D)

510(k) K102256

Diagnostic Ultrasound Indications for Use Form

GE Compact Ultrasound with 6S-RS Transducer

LOGIQ *i*, LOGIQ *e*, Vivid *e*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse†	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ [2]											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac[3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify) [4]											
Other[5]	P	P	P	P	P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN and Urological

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] For detection of fluid and pleural motion/sliding;

[5] Other use includes Urology/Prostate

[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[†] Coded Pulse is for digitally encoded harmonics .

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Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

Mark D. O'Kane for David G. Brown

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Office of In Vitro Diagnostic Device
Evaluation and Safety

Prescription Use (21 CFR 801 Subpart D)

510(k) K102250

Diagnostic Ultrasound Indications for Use Form

GE Compact Ultrasound with P2D Transducer

LOGIQ *i*, LOGIQ *e*, Vivid *e*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes[*]	Harmonic Imaging	Coded Pulse[†]	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]											
Pediatric											
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]				P							
Peripheral Vascular				P							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify)[4]											
Other[5]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN and Urological

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] For detection of fluid and pleural motion/sliding;

[5] Other use includes Urology/Prostate

[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[†] Coded Pulse is for digitally encoded harmonics .

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Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

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Evaluation and Safety

Prescription Use (21 CFR 801 Subpart D)

510(k) K102256

Diagnostic Ultrasound Indications for Use Form

GE Compact Ultrasound with 6Tc-RS Transducer

LOGIQ *i*, LOGIQ *e*, Vivid *e*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse*	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]											
Pediatric											
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	N	N	N	N	N	N	N	N	N	N	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify) [4]											
Other[5]											
Exam Type, Means of Access											
Transesophageal	N	N	N	N	N	N	N	N	N	N	
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN and Urological
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[4] For detection of fluid and pleural motion/sliding;
[5] Other use includes Urology/Prostate
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.
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